EXHIBIT 2

Exhibit 5, Affirmation of Eric M. Lindenfeld in support of Plaintiffs' Memorandum of Law in Opposition to Defendants' Motions for Summary Judgment Regarding Proof of Causation (Mot. Seq. #146, 159, 161, 147, 148, 149, 150, 151, 153, 154, 155, 156, 158, 160, 164)

EXPERT REPORT

Failures by Distributors and Manufacturers of Controlled Substances Doing Business in New York to Maintain Effective Controls to Prevent Diversion of and to Identify, Report, and Block Suspicious Orders for Schedule II Opioid Drugs

Evidence and Analysis as of December 2019

Submitted by
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A. Applicable Regulatory Mechanisms

1. The Federal Controlled Substances Act

Each distributor owes a duty to ***maintain effective control*** against diversion of prescription opiates into the illicit market. 21 U.S.C.A. § 823(b)(1) [1970].

The Controlled Substances Act and its implementing regulations create restrictions on the distribution of controlled substances. *See* 21 U.S.C. §§ 801–971 (2006); 21 C.F.R. §§ 1300–1321 (2009). The main objectives of the CSA are to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels. To effectuate these goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. The CSA categorizes all controlled substances into five schedules. The drugs are grouped together based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body. Each schedule is associated with a distinct set of controls regarding the manufacture, distribution, and use of the substances listed therein. The CSA and its implementing regulations set forth strict requirements regarding registration, labeling and packaging, production quotas, drug security, and recordkeeping.[5]

The CSA authorizes the DEA to establish a registration program for manufacturers, distributors, and dispensers of controlled substances designed to prevent the diversion of legally produced controlled substances into the illicit market.[6] Any entity that seeks to become involved in the production or chain of distribution of controlled substances must first register with the DEA.[7]

The CSA provides for control by the Justice Department of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain ***illegal***.[8] "Congress was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic."[9]

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[5] *Gonzales v. Raich*, 545 U.S. 1, 12–14 (2005) (internal citations omitted).

[6] H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970); *see* 21 U.S.C. § 801(2); 21 U.S.C. §§ 821-824, 827, 880.

[7] 21 U.S.C. § 822; 21 C.F.R. § 1301.11.

[8] 1970 U.S.C.C.A.N. 4566, 4569 (emphasis added).

[9] *United States v. Moore*, 423 U.S. 122, 135 (1975).

Distributors of Schedule II drugs—controlled substances with a "high potential for abuse"[10] – must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."[11] The CSA is designed to improve the administration and regulation of the manufacturing, distribution, and dispensing of controlled substances by providing for a "closed" system of drug distribution for legitimate handlers of such drugs. **Such a closed system is intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market**, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[12] The CSA seeks, through appropriate regulation of the manufacture and distribution of drugs, to reduce the availability of drugs subject to abuse except through legitimate channels of trade and for legitimate uses.[13]

2. CSA Regulatory Framework

Each distributor "shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[14]

This regulatory duty has been defined to include the following obligations:

> The "***security requirement***" at the heart of this case mandates that distributors "design and operate a system" to identify "suspicious orders of controlled substances" and report those orders to DEA (the ***Reporting Requirement***). 21 C.F.R. § 1301.74(b). The Reporting Requirement is a relatively modest one: It requires only that a distributor provide basic information about certain orders to DEA, so that DEA "investigators in the field" can aggregate reports from every point along the legally regulated supply chain and use the information to ferret out "potential illegal activity." *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007). Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some "due diligence" and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the ***Shipping Requirement***).[15]

The regulatory duty is not difficult to follow and understand. One who voluntarily applies to become a registrant must submit an application and undergo a pre-registration investigation.

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[10] 21 U.S.C. §§ 812(b), 812(2)(A)-(C)

[11] 21 U.S.C. § 823(b)(1).

[12] 1970 U.S.C.C.A.N. 4566, 4571-72.

[13] 1970 U.S.C.C.A.N. 4566, 4574.

[14] 21 C.F.R. § 1301.74(b) [1971].

[15] *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 212–13 (D.C. Cir. 2017) (emphasis added).

The pre-registration investigation involves a through onsite inspection of the registrant's facilities as well as extensive discussions of the applicable regulations and the security requirements that must be followed—***however,*** DEA pre-registration investigations do not serve to validate the effectiveness of a distributor's or manufacturer's SOMS, which those registrants are solely responsible for designing and implementing in a manner that will maintain effective controls against diversion and ensure the identification, reporting, and blocking of suspicious orders.

While there are numerous requirements related to registration, my opinions focus on the following compliance requirements:

- Maintain effective controls to prevent the diversion of controlled substances into "other than legitimate medical, scientific, and industrial channels";
- "Design and operate" a system to identify suspicious orders; and
- Report suspicious order "when discovered."

3. MDL2804 Discovery Ruling 12

The Court in the Ohio multidistrict litigation issued a discovery ruling (Discovery Ruling 12) which outlines the statutory and regulatory duties imposed by federal law upon distributors of controlled substances.[16] The ruling addresses the following legal standards:

> Distributors of opioids are required to "'design and operate a system' to identify 'suspicious orders of controlled substances' and report those orders to DEA (the Reporting Requirement)." *Masters Pharmaceutical*, 861 F.3d 206, 212 (D.C. Cir. 2017) (quoting 21 C.F.R. § 1301.74(b)). Federal regulations explain that "suspicious orders include [among others] orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b). Thus, an order for opioids received by a distributor from a retail pharmacy may qualify as "suspicious" for any of a number of different reasons.[17]

[16] See Discovery Ruling No. 12 regarding Suspicious Order Interrogatory [Doc. 1174].

[17] "Of course, an order may be suspicious for other reasons, even if it doesn't fit the Monthly Total Rule, such as that the pharmacy-customer "submitted more order forms in a 30-day period than it had in any of the prior six calendar months [the 'Order Form Rule'], or if the timing of the order did not comport with the customer's general ordering pattern over those six months [the 'Order Timing Rule']." *Id.* There are many other algorithms a distributor could use to identify opioid orders as suspicious, including: (1) the order for the opioid was placed within 30 days of an earlier suspicious order for the same opioid (the "Consecutive Order Rule"); (2) the order for the opioid was placed within 30 days of an order for the same opioid from a different distributor (the "Multi-Distributor Rule"); (3) the percentage increase in the amount of opioid ordered exceeded a certain threshold (the "Percentage Increase Rule"); or (4) the amount of opioid ordered exceeded by some threshold the amounts ordered by other similar or nearby pharmacies ("the Pharmacy Comparison Rule").

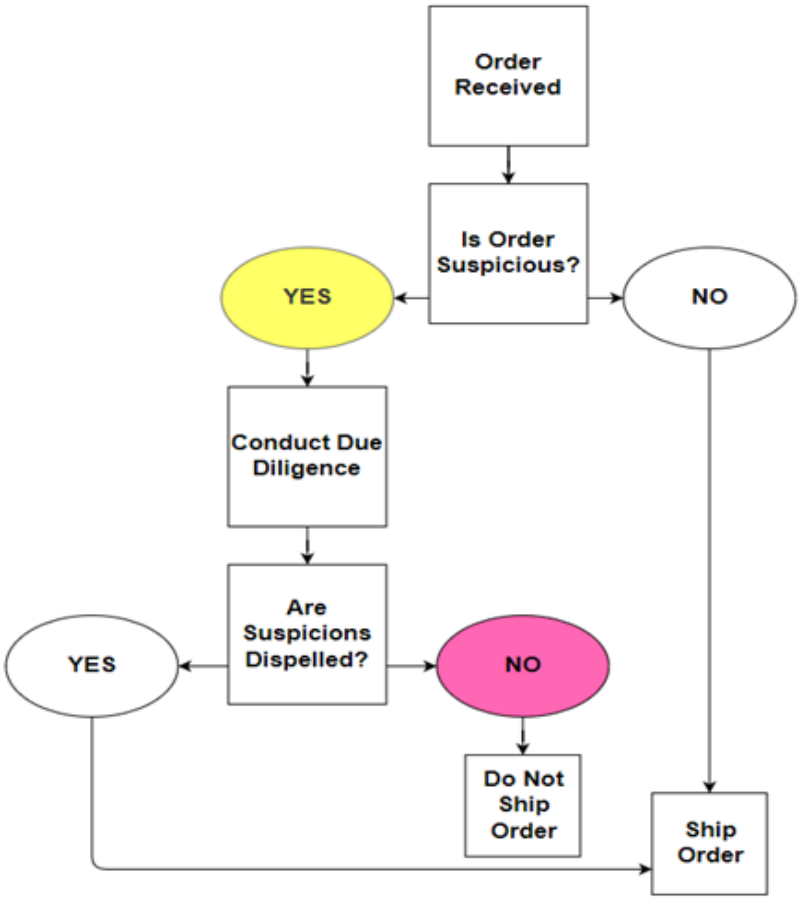
The simplest example is that a given order for an opioid may be suspicious if it was of "unusual size" – say, an order that pushed a pharmacy's monthly total number of opioid doses to exceed the monthly totals the same pharmacy had ordered in the prior six months. The Order refers below to this algorithm as the "Monthly Total Rule." (*Masters Pharmaceutical* described the "Monthly Total Rule" as follows: an order is suspicious if "that order—combined with other orders placed in the same 30-day period—requested more doses of a controlled medication than the pharmacy had requested in any of the previous six calendar months." *Id.* at 213.)

As noted, once it has identified a suspicious order, a distributor is required to report it to the Drug Enforcement Agency ("DEA"). *See* 21 C.F.R. §1301.74(b) ("The [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the [distributor]."). Furthermore, having received a suspicious order, the distributor "must make one of two choices: decline to ship the [suspicious] order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the Shipping Requirement)." *Id.* at 212–13. Of course, a distributor's due diligence efforts must be thorough: "the investigation must dispel all red flags indicative that a customer is engaged in diversion to render the order non-suspicious and exempt it from the requirement that the distributor 'inform' the Agency about the order. Put another way, if, even after investigating the order, there is any remaining basis to suspect that a customer is engaged in diversion, the order must be deemed suspicious and the Agency must be informed." *Masters Pharmaceuticals, Inc.*, Decision and Order, 80 Fed. Reg. 55418-01 at *55477 (DEA Sept. 15, 2015) (hereinafter, "*Decision and Order*"). Indeed, the DEA may revoke a distributor's certificate of registration as a vendor of controlled substances if the distributor identifies orders as suspicious and then ships them "without performing adequate due diligence." *Masters Pharmaceuticals*, 861 F.3d at 212.[18]

"*See also Masters Pharmaceuticals, Inc.*, Decision and Order, 80 Fed. Reg. 55418-01 at *55477 (DEA Sept. 15, 2015) ("a pharmacy's business model, dispensing patterns, or other characteristics might make an order suspicious, despite the particular order not being of unusual size, pattern or frequency. In other words, orders placed by a pharmacy that engages in suspicious activity, but places orders of regular size, pattern, and frequency, could still be deemed suspicious."); *id.* at *55478 (noting that "suspicion" is a low bar: it "is simply a far lower standard of proof than whether it is 'likely' that the circumstance exists," and "the regulation's adoption of suspicion as the threshold for triggering the requirement that a distributor inform the Agency about the order does not even rise to the level of probable cause.")" Discovery Ruling No. 12, fn 2.

[18] Discovery Ruling No. 12 [Doc. 1174]. *See also*, *id.*, at n.3 ("The *Decision and Order* was a final order entered by the DEA revoking Masters Pharmaceutical's certificate of registration, without which Masters Pharmaceutical could not sell controlled substances. In *Masters Pharmaceutical*, the D.C. Circuit Court of Appeals denied a petition for review, leaving intact the DEA's analysis and conclusion in the *Decision and Order*.")

The Order noted the "legal authorities reviewed above leave unclear exactly when an order is deemed suspicious, and thus when a distributor is required to inform the DEA that it received a suspicious order. The following flowchart illustrates the issue."[19]



This flowchart shows how a distributor's Suspicious Order Monitoring System must work and diagrams the process a distributor must undertake when it receives a suspicious order. Notably, there is a "yellow light" (caution) and a "red light" (stop) in the process. When a distributor first identifies an order as suspicious, this is a "yellow light" – it cannot ship the order without doing some investigation. If that investigation does not "dispel all red flags indicative that a customer is engaged in diversion," then the distributor gets a "red light" and must not ship the order. *Masters Pharmaceutical*, 861 F.3d at 222. Beyond requiring that a distributor must employ *some* Suspicious Order Monitoring System

[19] *See* Discovery Ruling No. 12 issued December 9, 2018 at page 5.

("SOMS"), the federal regulations do not make explicit exactly what algorithm(s) the SOMS must use to identify suspicious orders, or exactly what due diligence efforts are required when investigating an order after it is identified as suspicious. For example, a distributor is not *required* to use the Monthly Total Rule or the Pharmacy Comparison Rule; it is free to design its SOMS using any algorithms and rules it believes will get the job done.

With regard to the Reporting Requirement, it is not entirely clear whether a distributor's obligation to inform the DEA attaches: (1) when the "yellow light" flashes – that is, when the distributor first identifies an order as suspicious; or (2) only after the "red light" flashes – which would mean a distributor does not have to inform the DEA it received a suspicious order if investigation shows the order was legitimate, after all. Indeed, the authorities cited above provide support for each approach, as shown by the following quotations.

"Red Light"

- "[I]f, ***even after investigating the order***, there is any remaining basis to suspect that a customer is engaged in diversion; the order must be deemed suspicious and the Agency must be informed. *Decision and Order*, 80 Fed. Reg. at *55478.

- "DEA regulations expressly provide that deviations in size, frequency, or pattern are the sort of indicia that give rise to a suspicion and, ***unless the suspicion is dispelled***, the obligation to report. *Masters Pharmaceuticals*, 861 F.3d at 215 (citing *Decision and Order*, 80 Fed. Reg. at *55,479; and 21 C.F.R. §1301.74(b)).

"Yellow Light"

- "***Once a distributor has reported a suspicious order***, it must make one of two choices: decline to ship the order or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the Shipping Requirement)." *Masters Pharmaceutical*, 861 F.3d at 212–13.[20]

In other words, the Court determined it is unclear whether an order is "suspicious" (and so must be reported to the DEA) as soon as a distributor's SOMS flags it as suspicious, or only after due diligence fails to dispel any suspicion. In any event, it is clear that distributors are required to identify suspicious orders from pharmacies and cannot ship those orders unless they conduct "due

[20] Discovery Ruling No. 12 [1174].

diligence" that determines those orders are not likely to be diverted. Further, distributors are required to report suspicious orders to the DEA upon discovery.

4. ARCOS/DADS

The Automated Records and Consolidated Orders System/Diversion Analysis and Detection System (ARCOS/DADS)[21] system is used to track and report the transfer of pharmaceuticals and to detect potential diversion. This system of records is maintained pursuant to the reporting requirements of the Comprehensive Drug Abuse Prevention and Control Act of 1970[22] and to fulfill the United States treaty obligations under the Single Convention on Narcotic Drugs and the Convention on Psychotropic Substances of 1971.[23]

The Automation of Reports and Consolidated Orders System (ARCOS) is the automated system developed by DEA to monitor selected controlled substances. ARCOS software enables the government to maintain a current and historical record of selected controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispenser level.[24]

The information contained in the ARCOS system consists of documentation of individual business transactions between individuals who handle controlled substances at every level, from manufacturers down to the pharmacies. Records include copies of controlled substances inventories, drug codes, deletion and adjustment reports, sales, and purchase orders, and includes, but not limited to the date of the transaction, the name, quantity, and quality of the chemicals/substances purchased or dispensed, the parties to the transaction, National Drug Codes (NDCs), and the DEA registrant numbers. This information provides an audit trail of all manufactured and/or imported controlled substances.

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[21] "ARCOS" refers to the automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level - hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions. Included in the list of controlled substance transactions tracked by ARCOS are the following: All Schedules I and II materials (manufacturers and distributors); Schedule III narcotic and gamma-hydroxybutyric acid (GHB) materials (manufacturers and distributors); and selected Schedule III and IV psychotropic drugs (manufacturers only). ARCOS accumulates these transactions which are then summarized into reports which give investigators in Federal and state government agencies information which can then be used to identify the diversion of controlled substances into illicit channels of distribution. The information on drug distribution is used throughout the United States (U.S.). by U.S. Attorneys and DEA investigators to strengthen criminal cases in the courts. *See* United States Department of Justice, Drug Enforcement Administration, Diversion Control Division, Automation of Reports and Consolidated Orders System (ARCOS), *Background: What is ARCOS and What Does it Do?*, https://www.deadiversion.usdoj.gov/arcos/#background (last visited September 7, 2017).

[22] 21 U.S.C. 826(d).

[23] 69 FR 51104-02.

[24] *See* ARCOS Registrant Handbook, United States Department of Justice, Drug Enforcement Administration, Office of Diversion Control, Section 1.1.1, *ARCOS Defined* (Version 1.0 August 1997).

All automated data files associated with ARCOS/DADS are maintained in the Department of Justice Data Center and the Drug Enforcement Administration Data Center and the system is located at Drug Enforcement Administration, 700 Army Navy Drive, Arlington, VA 22202. 69 FR 51104-02.

The ARCOS/DADS system uniquely has access to ***all*** of the data submitted by each DEA registrant in the country.[25] These distribution transactional records are compiled by the DEA through a portal and the data is compiled by DEA in accordance with law for determining quota, distribution trends, internal audits, inspection, investigations and other analyses.[26] Additionally, the DEA provides internet access to summary data from this system.

In the multidistrict litigation in Ohio, the DOJ/DEA disclosed the national ARCOS database to the Plaintiffs' Executive Committee (2006-2014) and that additional transactional data was independently disclosed by some of the defendants. It is my understanding that both sets of data were then uploaded to a database managed by Craig McCann, another expert retained here. I have included data derived from and provided by Mr. McCann in the application of the methodologies identified in this report.

The ARCOS data, defendants' transactional data, and application of the methodologies I identified are consistent with the types of data, facts, information, and reports I would typically rely on in conducting the analysis and reaching the opinions contained herein. I am very familiar with the ARCOS data and defendants' transactional data and have experience analyzing the data and reports generated therefrom. I have reviewed Mr. McCann's methods and reports and they are consistent with my understanding, based on my experience, of how the data should be analyzed.

5. DEA DIVERSION INVESTIGATOR'S MANUAL

The DEA published a manual providing further guidance related to the CSA and its regulations. Portions of the manual have previously been publicly available and accurately set forth the charge for DEA investigators, as follows:

> Registrants, who routinely report suspicious orders, yet fill these orders, with reason to believe they are destined for the illicit market, are expressing an attitude of irresponsibility that is a detriment to the public health and safety as set forth in 21 U.S.C. 823 and 824. Suspicious orders include those which are in excess of legitimate medical use or exhibit characteristics leading to possible diversion such as: orders of unusual size, unusual frequency, or those deviating substantially from a normal pattern. ***The supplier can determine whether the order is excessive by checking their own sales and establishing the average amount of controlled substances shipped to registrants of the same apparent***

[25] The DEA maintains the Automation of Reports and Consolidated Orders System ("ARCOS"), an official automated comprehensive drug reporting system that monitors the flow of DEA controlled substances from their point of manufacture through commercial channels to the point of sale or distribution at the dispensing/retail level. Drug wholesalers do not have access to the ARCOS data or to the data of other wholesalers and distributors. *Keysource Med., Inc. v. Holder*, No. 1:11-CV-393, 2011 WL 3608097, at *2 (S.D. Ohio Aug. 16, 2011).

[26] https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/index.html

> ***size in a particular geographic area. If the customer exceeds this threshold, the request should be viewed as suspicious. This activity, over extended periods of time, would lead a reasonable person to believe that controlled substances possibly are being diverted.*** An investigation will be conducted for possible violation of the CSA and regulations upon determining that the reporting registrant, as a general practice, does not voluntarily halt shipments of controlled substances to registrants involved in suspected diversion or to registrants against whom previous action has been taken. In these instances, the registrant is subject to the appropriate prosecution and/or administrative action.[27]

Importantly, the DEA does not approve or disapprove supplier shipments of controlled substances:

> C. DEA field offices will not approve or disapprove a registrant's shipment of controlled substances, nor their procedures for detecting suspicious orders. The responsibility for detecting suspicious orders and making the decision to ship rests solely with the registrant. . . .
>
> D. Registrants can verify the current status and accuracy of a customer's registration via the official Diversion Website in making an independent decision on whether to ship controlled substances. The web site is: https://www.deadiversion.usdoj.gov/webforms/validateLogin.jsp and is a free service provided to the registrant.

As the DEA manual explicitly states, the responsibility for making the decision to ship rests with the supplier.[28] [29]

6. DEA DISTRIBUTOR INITIATIVE BRIEFINGS.

In August 2005, Drug Enforcement Administration designed and implemented the DEA Distributor Initiative. The initiative was in response to the growing number of rogue Internet pharmacies illegally dispensing controlled substances and their pattern of purchasing extremely large amounts of a limited type of controlled substances from distributors. This program consisted of an individual meeting between the DEA and distributors to re-iterate to DEA registrants their

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[27] *See* DEA Diversion Investigators Manual (1996) (CAH_MDL2804_02203353, CAH_PRIORPROD_DEA07_01176914 at 01176957) ; *see also* DEA Diversion Manual (1990) (CAH_PRIORPROD_DEA_01176247 at 01176301); DEA Diversion Investigators Manual (2011) (CAH_MDL2804_00953317 at 00953396, CAH_MDL2804_01483146, CAH_MDL2804_01563592) ("By its very nature, an order is a request to purchase controlled substances and has not yet been filled. Reporting a filled order is potentially allowing controlled substances to be diverted. Therefore, suspicious orders will not be filled.")

[28] See DEA Diversion Investigators Manual (1996) (CAH_MDL2804_02203353, CAH_PRIORPROD_DEA07_01176247); see also DEA Diversion Investigators Manual (2011) (CAH_MDL2804_00953317, CAH_MDL2804_01483146, CAH_MDL2804_01563592).

[29] At the request of DEA/DOJ, Plaintiffs have removed a section of this Report based on DEA/DOJ's claim that a claw-back of a document cited in the removed section is forthcoming.

responsibilities under the Controlled Substances Act and Code of Federal Regulations and to discuss current trends and methods of diversion.

In February 2014, at a conference in North Carolina, DEA Deputy Assistant Administrator Joseph T. Rannazzisi reported that the DEA had conducted distributor briefings to 81 registrants that had a total of 233 registered locations. The DEA has produced in discovery summaries of some of these meetings as follows:

Memorandum, Meeting with Cardinal Health, Inc. Concerning Interact Pharmacies on August 22, 2005;[30]

Memorandum, Conference Call with. Mr. John. Gilbert of McKesson Corp. on November 28, 2005;[31]

Memorandum, Meeting Between Office of Diversion Control (OD) and McKesson Corp. on January 3, 2006;[32]

Memorandum, Internet Presentation; with AmerisourceBergen on August 10, 2005;[33] and

Memorandum, Distributor Initiative Briefing with AmerisourceBergen Drug on May 16, 2017.[34]

At these briefings DEA personnel would reiterate the registrant's requirement to maintain effective controls to prevent diversion as required in U.S.C. 21 § 843(e) and 21 C.F.R. § 1301.71(a). During these meetings the DEA specifically focused on discussing 21 C.F.R. § 1301.74(b) which states, "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

DEA also advised the registrant at these meetings that DEA cannot tell a distributor if an order is legitimate or not.[35] The distributor has the responsibility to determine which orders are suspicious and once identified they should report those orders to DEA and should not distribute suspicious orders.[36] Further, it was reiterated that a distributor was advised prior to shipping any order that was determined to be suspicious, the distributor should conduct a due diligence investigation to insure the controlled substances in the order are not likely to be diverted and

[30] US-DEA-00000352.

[31] US-DEA-00000369.

[32] US-DEA-00000371.

[33] US-DEA-00000147.

[34] US-DEA-00000144

[35] US-DEA-00000352, 00000360.

[36] *Id.*

document their due diligence actions.[37] Failure to do so could result in action against their DEA registration.

7. DEA GUIDANCE LETTER

In September 2006, in response to the nationwide growing health problems involving diversion of controlled substances, DEA Deputy Assistant Administrator Joseph T. Rannazzisi forwarded a letter to all DEA registered distributors and manufacturers. The purpose of the letter was to reiterate the legal duties of distributors as DEA registrants and provide some examples of activities that may be indicative of diversion. [38]

Mr. Rannazzisi's letter referenced 21 U.S.C. 823(e) that restated the requirement that distributors and manufacturers have a legal requirement to maintain effective controls against diversion. Mr. Rannazzisi's letter further cited DEA Regulation 21 C.F.R. 1301.74(b) which states the requirement for a registrant to design and operate a system to disclose suspicious orders of controlled substances and to report suspicious orders to the D.E.A. when discovered. The system should be capable of identifying a suspicious order based on size, pattern and frequency and reporting that order to DEA. Contained in the written notification were a list of circumstances that may be indicative of diversion. Those circumstances listed the following:

a. Ordering excessive quantities of a limited variety of controlled substances.

b. Ordering a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered.

c. Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs.

d. Ordering the same controlled substances from multiple distributors.

The written communication also listed some guidance for a distributor by providing some possible inquiries of a customer's business activity that could be indicative of diversion. Mr. Rannazzisi further stated and reiterated:

> The DEA regulations require all distributors to report suspicious orders of controlled substances. Specifically, the regulations state in 21 C.F.R. 1301.74(b):
>
> > The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant.

[37] *See also Novelty Distributors, Inc.,* 73 Fed. Reg. 52,689, 52,669 (Drug Enf't Admin. September 3, 2008) ("Fundamental to its obligation to maintain effective controls against diversion, a distributor must review every order and identify suspicious transactions. Further, it must do so prior to shipping the products. Indeed, a distributor has an affirmative duty to forgo a transaction if, upon investigation, it is unable to determine that the proposed transaction is for legitimate purposes.").

[38] *See* CAH_MDL_PRIORPROD_DEA07_00837645.

> Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

It bears emphasis that the foregoing ***reporting requirement is in addition to, and not in lieu of the general requirement under 21 U.S.C. 823(e) that a distributor maintain effective controls against diversion.***

This, in addition to reporting all suspicious orders, ***a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels***. Failure to exercise such due diligence could, as circumstances warrant, provide a statutory basis for revocation or suspension of a distributor's registration.[39]

8. JUNE 2007 SOUTHWOOD PHARMACEUTICALS, INC. DISTRIBUTOR CASE

DEA Deputy Administrator Michele M. Leonhart issued an Order on June 22, 2007[40], detailing the revocation of DEA registration for Southwood Pharmaceuticals, Inc ("Southwood"). The Order further denied any pending applications for renewal or modification of registration because of the imminent danger to the public health or safety.

The language contained in this Order clearly re-iterated the requirement for a distributor to have a suspicious order monitoring program. The Order states the following, "a registrant must ''design and operate a system to disclose to the registrant suspicious orders of controlled substances''; suspicious orders must be reported to the local Field Division Office upon discovery by the registrant.[41] Under the regulation, suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.''

This Order also contains a description of the conduct of Southwood causing the revocation of their DEA registration as described in the Order to Show Cause and Immediate Suspension Order of Registration (OTSC/ISO) issued on November 30, 2006. The OTSC/ISO detailed that Southwood distributed controlled substances to customers they knew or should have known were diverting controlled substances. The OTSC/ISO stated Southwood repeatedly supplied excessive quantities of hydrocodone to fifteen pharmacies that were orders of unusual size and frequency as well as substantially deviating from the normal pattern. The OTSC/ISO further stated Southwood never reported any of the orders as suspicious to the DEA.

The OTSC/ISO also stated that Michael Mapes of the DEA conducted a meeting with Southwood by conference call on July 17, 2006. The content of the meeting described in the OTSC/ISO is consistent with the DEA Distributor Program being conducted by the DEA and described in this timeline. During this meeting Mr. Mapes discussed the purchasing activities of

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[39] *See id.* (emphasis added).

[40] *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007).

[41] 21 CFR 1301.74(b).

several pharmacies who were customers of Southwood. During this meeting Mr. Mapes also provided Southwood with a description of illegal conduct of Internet pharmacies and described factors to consider when assessing customers for diversion. These factors included the size and frequency of order, range of product order, and the percentage of control substances ordered when compared to non-controlled substances. Mr. Mapes further discussed the factors that are required to ensure a prescription is legally prescribed by a physician.

The following statement is contained in the OTSC/ISO, "a pattern of drugs being distributed to pharmacies [which] are diverting controlled substances demonstrates a lack of effective controls against diversion by the distributor" and could lead to the revocation of the distributor's registration." Mr. Mapes further stated, "… any distributor who was selling controlled substances that are being dispensed outside the course of professional practice must stop that distribution immediately."[42]

The OTSC/ISO stated Mr. Mapes discussed with Southwood representatives whether it could ship an order which it had reported as suspicious. Mr. Mapes advised Southwood representatives if they reported a suspicious order to the D.E.A. they still needed to make the decision as to whether to ship the order. The OTSC/ISO further detailed that Southwood representatives asked Mr. MAPES whether they should stop shipping controlled substances to the internet pharmacies and Mr. MAPES replied the DEA cannot tell a distributor whether a particular order is legitimate or not, and whether to ship was "a business decision," but Southwood had an obligation to ensure that the controlled substance being distributed were used for legitimate medical purposes.

9. DECEMBER 2007 DEA GUIDANCE LETTER

In December 2007, DEA Deputy Assistant Administrator for the Office of Diversion Control, Joseph T. Rannazzisi issued a second letter to all DEA registered distributors and manufacturers restating much of the information contained in the previous letter.[43]

This letter was focused on reiterating the responsibilities of manufacturers and distributors to inform DEA of suspicious orders as required by 21 CFR 1301.74(b).

The letter re-iterated that 21 CFR 1301.74(b) requires a manufacturer or distributor to design and operate a system to disclose to the registrant suspicious order of controlled substances. The letter further notified registrants it is the sole responsibility of registrants to design and operate the system. The letter advised registrants of the following, "Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for report suspicious orders, should no longer be taken to mean that DEA approves a specific system."

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[42] *Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 Fed. Reg. 36,487, 36,492(Drug Enf't Admin. July 3, 2007).

[43] CAH_MDL_PRIORPROD_DEA07_00092296.

The letter also notifies that filing a monthly report of transactions to the DEA, often referred to as excessive purchase reports, does not meet the regulatory requirement to report suspicious orders.

The letter also reiterated the following requirements:

1. 21 CFR 1301.74(b) requires DEA registrants inform the DEA of suspicious order when discovered by the registrant.

2. DEA registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine if the controlled substances are likely to be diverted.

3. The regulation states suspicious orders include orders of an unusual size, deviating substantially from a normal pattern, and orders of an unusual frequency. The criteria are disjunctive and are not all inclusive.

4. DEA registrants who routinely report suspicious orders, yet fill these orders without first determining whether the orders are not being diverted may be failing to maintain effective controls against diversion that may result in possible action against their DEA registration.

10. DEA ADMINISTRATIVE ACTIONS

Distributors and manufacturers in this industry regularly monitor DEA administrative actions involving maintenance of effective controls against diversion and failure to identify and/or report suspicious orders. There are many different types of sources that make the details of DEA administrative action available for the industry to review. The type of information available can be a very in-depth article or publications simple as a press releases. Two examples of an in-depth sources of information is the information published in the Federal Register involving DEA cases against Masters Pharmaceutical Inc. and Southwood Pharmaceuticals Inc.

The DEA posts administrative case information on the Internet on their website at www.deadiversion.usdoj.gov. The DEA and Department of Justice also normally issue press releases on administrative actions that subsequently generate media coverage and reviews by law firms. Further, trade organizations like The Healthcare Distribution Alliance typically publish articles regarding DEA administrative action for review by their members. Typically, when a DEA administrative action occurs, there are several law firms that closely follow the industry and they post articles on their websites that describe the action and offer opinions of future impact to the industry.

Listed below are some of the significant administrative action against distributors and manufacturers for failing to maintain effective controls against diversion and for failing to identify and/or reports suspicious orders:

1. April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007,

AmerisourceBergen entered into a settlement and release agreement with the DEA related to the allegations made by the agency.[44]

2. June 22, 2007, the DEA revoked the Registration of Southwood Pharmaceuticals, Inc. 72 Fed. Reg. 36,487 (Department of Justice; Southwood Pharmaceuticals, Inc.; Revocation of Suspension (July 2, 2007)) on Tuesday, July 3, 2007 July 3, 2007, Department of Justice, Drug Enforcement Administration article in the Federal Register, titled, Southwood Pharmaceuticals, Inc.; Revocation of Registration.[45]

3. November 29, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center which suspended their DEA registration for failure to maintain effective controls against diversion of hydrocodone.[46]

4. December 7, 2007, DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of hydrocodone.[47]

5. December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center for failure to maintain effective controls against diversion of hydrocodone.[48]

6. January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Health Stafford, Texas Distribution Center for failure to maintain effective controls against

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[44] AmerisourceBergen Corporation, *AmerisourceBergen Signs Agreement with DEA Leading to Reinstatement of its Orlando Distribution Center's Suspended License to Distribute Controlled Substances*, June 22, 2007, available at http://investor.amerisourcebergen.com/news-releases/news-release-details/amerisourcebergen-signs-agreement-dea-leading-reinstatement-its (last visited March 11, 2019).

[45] *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007) (*also available at* https://www.deadiversion.usdoj.gov/fed_regs/actions/2007/fr07032.htm (last visited March 10, 2019)).

[46] Cardinal Health, Press Release, *Cardinal Health Receives DEA Order to Temporarily Cease Distribution of Controlled Substances from Auburn Wash. Facility*, November 29, 2007, available at (Source: https://ir.cardinalhealth.com/news/press-release-details/2007/Cardinal-Health-Receives-DEA-Order-to-Temporarily-Cease-Distribution-of-Controlled-Substances-from-Auburn-Wash-Facility/default.aspx (last visited March 11, 2019).

[47] Cardinal Health, Press Release, *Cardinal Health to Cease Distribution of Controlled Substances from Florida Facility,* December 7, 2007, available at https://cardinalhealth.mediaroom.com/newsreleasearchive?item=122500 (last visited March 8, 2019).

[48] Drug Topics, "DEA hits third Cardinal Health distribution center," December 21, 2007, available at https://www.drugtopics.com/pharmacy/dea-hits-third-cardinal-health-distribution-center (last visited March 8, 2019).

diversion of hydrocodone. Cardinal agreed to suspend shipping any controlled substances from the location pending a resolution with the DEA.[49]

7. May 2, 2008, McKesson Corporation agree to pay a $13 million civil penalty and entered into an Administrative MOA with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program.[50]

8. On September 30, 2008, Cardinal Health agreed to pay a $34 million civil penalty and entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement (MOA) with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The MOA also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances.[51]

9. January 9, 2009, Rite Aid agreed to pay $5 Million in civil penalties to resolve allegations that Rite Aid knowingly filled prescriptions for controlled substances that were not issued for legitimate medical purposes; failed to notify the DEA of significant thefts and losses of controlled substances; failed to maintain or failed to furnish to the DEA upon request records required to be kept under the Controlled Substances Act for a period of two years; and failed to properly execute DEA forms used to ensure the amount of Schedule II drugs ordered by Rite Aid were actually received violations of the Controlled Substances Act in eight states.[52]

10. April 21, 2009, Settlement and Release Agreement and Administrative Memorandum of Agreement between DOJ/DEA and Masters Pharmaceutical Inc.[53]

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[49] Drug Topics, "Cardinal caught between DEA and pharmacies over diversion control," April 14, 2008, available at https://www.drugtopics.com/community-practice/cardinal-caught-between-dea-and-pharmacies-over-diversion-control (last visited March 9, 2019).

[50] Settlement and Release Agreement and Administrative Memorandum of Agreement, entered into May 2, 2008, between DEA and McKesson Corporation, available at https://www.dea.gov/sites/default/files/ 2018-06/Pharmaceutical%20Agreements%20-%20McKesson%20-%202008_0.pdf (last visited March 19, 2019).

[51] United States Attorney's Office. (October 2, 2008) *Cardinal Health Inc., Agrees to Pay $34 Million to Settle Claims That It Failed to Report Suspicious Sales of Widely-Abused Controlled Substances* [Press Release]. Available at https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html (last visited March 10, 2019).

[52] United States Department of Justice, (January 12, 2009) *Rite Aid Corporation and Subsidiaries Agree to Pay $5 Million in Civil Penalties to Resolve Violations in Eight States of the Controlled Substances Act* [Press Release]. Available at https://www.justice.gov/opa/pr/rite-aid-corporation-and-subsidiaries-agree-pay-5-million-civil-penalties-resolve-violations (last visited March 8, 2019).

[53] Settlement and Release Agreement and Administrative Memorandum of Agreement between DEA and Masters Pharmaceutical, Inc. Available at https://www.dea.gov/sites/default/files/2018-

11. June 15, 2010, Order to Show Cause – Immediate Suspension Order served to The Harvard Drug Group, Livonia, MI.[54]

12. June 10, 2010, DEA suspended Sunrise Wholesale, Inc. from selling controlled substances for supplying excessive amounts of oxycodone to "pill mills."[55]

13. October 13, 2010, settlement was reached between the DEA and CVS Pharmacy, Inc. resolving the criminal investigation of unlawful distribution and sales of pseudoephedrine ("PSE") by CVS/pharmacy stores in Southern California and Nevada and a CVS/pharmacy distribution center in Southern California. CVS paid a penalty of $75,000,000.00 and forfeited $2.6 million in profits for a total payment of $77.6 million.[56]

14. April 18, 2011, Harvard Drug Group agreed to pay $8,000,000 in civil penalties as part of settlement with DEA related to allegations that Harvard failed to have in place an effective system for identifying suspicious orders of controlled substances, violating the Controlled Substances Act.[57]

15. June 10, 2011, Order to Show Cause and Immediate Suspension Order served on Keysource Medical Inc. Keysource Medical distributed 48 million doses of oxycodone products to Florida Pharmacies.[58]

06/Pharmaceutical%20Agreements%20-%20Masters%20Pharmaceutical%20-%202009.pdf (last visited March 19, 2019.

[54] Administrative Memorandum of Agreement between DEA and The Harvard Drug Group, LLC dated March 28, 2011. Available at https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20Harvard%20Drug%20Group%20-%202011.pdf (last visited March 19, 2019).

[55] LaMendola, Bob. "DEA accuses Sunrise company of supplying painkillers to 'pill mills.'" Sun-Sentinel. June 22, 2010. Available at https://www.sun-sentinel.com/business/fl-xpm-2010-06-22-fl-drug-wholesaler-stopped-20100621-story.html (last visited March 19, 2019).

[56] United States Attorney's Office. (October 14, 2010) *CVS Admits Illegally Selling Pseudoephedrine to Criminals who made Methamphetamine, Agrees to Pay $77.6 Million to Resolve Government Investigation* [Press Release]. Available at https://www.justice.gov/archive/usao/cac/Pressroom/pr2010/148.html (last visited March 19, 2019).

[57] United States Drug Enforcement Administration. (April 18, 2011) *Michigan Based Pharmaceutical Wholesaler Harvard Drug Group to Pay $8,000,000 in Settlement* [Press Release]. Available at https://www.dea.gov/press-releases/2011/04/18/michigan-based-pharmaceutical-wholesaler-harvard-drug-group-pay-us (last viewed on March 19, 2019).

[58] United States Drug Enforcement Administration. (June 10, 2011) *Cincinnati Pharmaceutical Supplier's DEA License Suspended* [Press Release]. Available at https://www.dea.gov/press-releases/2011/06/10/cincinnati-pharmaceutical-suppliers-dea-license-suspended (last visited March 11, 2019).

16. July 6, 2011, Order Denying Plaintiff's (Keysource Medical) Motion for Temporary Restraining Order and for Preliminary Injunction.[59]

17. February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of oxycodone.[60]

18. March 7, 2012, Memorandum of Opinion [Doc. 32] from the United States District Court for the District of Columbia, *Cardinal Health, Inc., vs. Eric H. Holder, Jr.*, Civil Action No. 12-185 (RBW), denying Cardinal's challenge of the DEA's Order to Show Cause and Immediate Suspension of Registration of Cardinal's Lakeland Distribution Center.[61]

19. April 5, 2012, a United States Attorney Office press release stated Keysource Medical agreed to pay a $320,000 fine for failing to guard against diversion of controlled substances and states Keysource Medical agreed to voluntarily surrender their DEA registration in September 2011.[62]

20. May 14, 2012, Cardinal Health entered into an Administrative MOA with the DEA, which, among other things, stipulated that its compliance with the terms of the 2008 MOA were inadequate in certain respects and that its Lakeland, Florida Distribution Center's DEA registration would be suspended for two years.[63]

21. March 28, 2013, settlement was reached among the United States and the DEA and CVS Pharmacy, Inc. and Oklahoma CVS Pharmacy, L.L.C., to resolve claims that CVS violated the CSA by: (1) filling prescriptions for certain prescribers whose DEA registration numbers were not current or valid; (2) entering and maintaining invalid DEA registration numbers on CVS dispensing records for certain prescriptions, which were at times provided to state prescription drug monitoring programs; and (3) entering and maintaining CVS dispensing records including prescription vial labels that identify a non-prescribing

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[59] *Keysource Medical, Inc., v. Attorney General of the United States, et al.*, No. 1:2011cv00393, *Order Denying Plaintiff's Motion for Temporary Restraining Order and for Preliminary Injunction* [Doc. 22], available at https://law.justia.com/cases/federal/district-courts/ohio/ohsdce/1:2011cv00393/147299/22/ (last visited March 11, 2019).

[60] 2012 Administrative Memorandum of Agreement entered into between DEA and Cardinal Health, CAH_MDL2804_02465982.

[61] Copy of Order available at https://www.govinfo.gov/content/pkg/USCOURTS-dcd-1_12-cv-00185/pdf/USCOURTS-dcd-1_12-cv-00185-0.pdf (last visited March 19, 2019).

[62] United States District Attorney's Office, Southern District of Ohio. (April 5, 2012) *Cincinnati Pharmaceutical Distributor to Pay $320,000 for Failing to Guard Against Diversion of Controlled Substances* [Press Release]. Available at https://www.justice.gov/archive/usao/ohs/news/04-05-12.html (last visited March 11, 2019).

[63] 2012 Administrative Memorandum of Agreement entered into between DEA and Cardinal Health, CAH_MDL2804_02465982.

provider as the prescribing provider for certain prescriptions. CVS paid a fine of $11,000,000.00.[64]

22. In July, 2013, the DEA initiated a regulatory investigation at CVS Indiana. After the investigation and after the DEA had informally indicated its displeasure with what it found at CVS, Mark NiCastro, the CVS Indiana Director of Operations, sent correspondence to the DEA. In the correspondence, Mr. NiCastro attempted to explain to the DEA why the CVS Indiana distribution center had never reported a suspicious order and he wrote:

> "In your recent email, you asked for information concerning CVS store orders that have been stopped outside of Indiana. Across the chain, the CVS SOM process has stopped and cancelled orders. I have attached the dates and the offices to which we reported these orders. As we discussed during the DEA audit and during our recent phone call, it is important to remember that CVS is shipping only to its own stores, and there are additional due diligence processes in our pharmacy operations group which monitor the dispensing of prescriptions across the entire CVS chain to ensure appropriate dispensing by stores. This is a primary contributor to the limited number of suspicious orders identified through our distributor SOM process."[65]

23. July 17, 2013, Walgreens agreed to pay $80 million in civil penalties related to allegations that Walgreens was filling numerous prescriptions that Walgreens employees knew, or should have known, were not issued for a legitimate medical purpose.[66]

24. June 19, 2014, In Regards to Masters Pharmaceutical the Administrative Law Judge issued a Recommended Decision in regards to the Order to Show Cause Hearing that occurred on February 24 through 28 and March 3 through 4, 2014. [67]

25. On September 2, 2014, settlement was reached among the United States and the DEA and CVS Pharmacy, Inc. The settlement resolved claims against CVS for filling from April 1, 2012 to July 31, 2012, 153 prescriptions at eight different pharmacies, written by Dr. Pedro Garcia during a time period during which his Texas Department of Public Safety Controlled Substances registration was expired. CVS paid a $1,912,500 fine.[68]

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[64] CVS-MDLT1-000060822 – 000060829.

[65] *See* NiCastro Depo. at 204-207; Ex. 42.

[66] United States Attorney's Office, Eastern District of New York. (July 17, 2013) *Eastern District U.S. Attorney's Office Participates in Record Settlement: Walgreens Agrees to Pay $80 Million in Civil Penalties Under the Controlled Substnaces Act* [Press Release]. Available at https://www.justice.gov/usao-edny/pr/eastern-district-us-attorney-s-office-participates-record-settlement-walgreens-agrees (last visited March 19, 2019).

[67] *Masters Pharm., Inc.*, 80 Fed. Reg. 55,418-55,501 (Drug Enf't Admin. Sept. 15, 2015).

[68] CVS-MDLT1-00060907 – 000060914.

26. On May 12, 2015, a settlement was reached among the United States and the DEA and CVS Health and all of its subsidiaries and affiliates. The settlement resolved claims that CVS failed "to fulfill its corresponding responsibility to ensure that CVS dispensed controlled substances only pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 CF.R. §1306.64." The settlement also covered CVS's "Florida Distribution Center[s] failure to maintain effective controls against the diversion of controlled substances into other than21 U.S.C. §823(e)" and failure to timely detect and report suspicious orders of controlled substances. CVS's conduct complained of is set forth in the February 2, 2012 Orders to Show Cause and Immediate Suspension Orders issued to CVS stores 219 and 5195. CVS paid a fine of $22,000,000.00.[69]

27. On July 24, 2015, a settlement was reached among the United States and the DEA and CVS Health to resolves claims that from May 1, 2013 through July 30, 2014, CVS failed to keep complete and accurate records of Schedule II controlled substances at a CVS store in Massachusetts in violation of 21 U.S.C. § 827(a)(3) and 21 C.F.R. §§ 1304.11(e)(3)(i), 1304.21, and 1304.22; and that CVS failed to report a March 14, 2014 robbery to the DEA within one business day in violation 21 C.F.R. § 1301.76(b). CVS paid a $50,000 fine.[70]

28. On August 7, 2015, a settlement was reached among the United States and the DEA and CVS Health. The settlement resolved claims that between March 3, 2010 and August, 2015 CVS stores in Rhode Island (1) filled prescriptions with invalid prescriber DEA number (knew or should have known in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.04); (2) filled prescriptions for Schedule III controlled substances written by psychiatric nurse practitioners who were not authorized under state law or by terms of their DEA registration to issue such prescriptions in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.03(a)(1); and (3) entering, creating, or maintaining CVS dispensing records in which the DEA registration numbers of non-prescribing practitioners, were substituted for the DEA registration numbers of prescribing practitioners in violation of 21 U.S.C. § 842(a)(5) and 21 C.F.R. § 1306.24. CVS paid a $450,000 fine.[71]

29. September 8, 2015, Masters Pharmaceutical – DEA Acting Administrator Chuck Rosenberg issued a Final Order revoking the DEA registration of Master Pharmaceutical Inc.[72]

30. On December 18, 2015, a settlement was reached among the United States and the DEA and CVS Pharmacy, Inc. The settlement was the result of a DEA inspection that was

[69] CVS-MDLT1-000060796 – 000060804.

[70] CVS-MDLT1-000099702 –000099704.

[71] CVS-MDLT1-000060847 – 000060855.

[72] *Masters Pharm., Inc.*, 80 Fed. Reg. 55,418-55,501 (Drug Enf't Admin. Sept. 15, 2015).

performed after CVS reported the theft of over 40,000 dosages of controlled substances by two former employees from a Texas CVS pharmacy. The inspection that was started due to theft demonstrated that CVS again failed its CSA obligations. CVS paid a fine of $345,000.00.[73]

31. On December 31, 2015, the DEA issued a letter of admonishment for violations in distributing HCPs at the CVS Indiana distribution center. This DEA finding was the result of the July 2013 investigation. Before the admonishment, Agent Gillen of the DEA sent an email to Mr. Nicastro outlining that CVS Store No. 6880 ordered 1,888,600 dosage units of hydrocodone between January 1, 2012 and October of 2013. The pharmacy is located in Vincennes, IN with a population of approximately 18,000 people. Additionally, he indicated that Store No. 6757 ordered 2,012,400 of hydrocodone tablets for Columbus, IN, which has a population of 45,000. Agent Gillen then writes: "Both stores have purchased a large quantity of Hydrocodone given their population."[74]

32. On February 12, 2016, a settlement was reached among the United States and the DEA and CVS Pharmacy, Inc. In the settlement, CVS acknowledged that between 2008 and 2012, "certain CVS/pharmacy retail stores in Maryland did dispense certain controlled substances in a manner not fully consistent with their compliance obligations under the CSA…" CVS paid a fine of $8,000,000.00.[75]

33. June 30, 2016, CVS agreed to pay $3.5 Million to resolve allegations that 50 of its stores violated the Controlled Substances Act by filling forged prescriptions for controlled substances – mostly addictive painkillers – more than 500 times between 2011 and 2014.[76]

34. On October 20, 2016, a settlement was reached among the United States and CVS Pharmacy, Inc. The settlement resolved claims from an investigation that the DEA began in January 2016. The DEA investigated two CVS stores in Connecticut. Although the offending conduct occurred after CVS quit distributing HCPs, it is indicative of the overall pattern and practice of CVS. The settlement resolves claims that CVS failed to keep paper Schedule III-V prescriptions either in a separate prescription file or readily retrievable from other prescription records, which allegedly violated 21 U.S.C. 827(b)(2)(A) and (B) and 21 C.F.R. 1304.04(h)(4) and failed to keep Schedule III-V purchase invoices on at least 31 occasions in separate or in a readily retrievable manner from all other records of the

[73] CVS-MDLT1-00060915-00060921.

[74] *See* CVS-MDLT1-00008014 – 00008015; CVS-MDLT1- 000076135.

[75] CVS-MDLT1-000060805-00060811.

[76] United States District Attorney's Office, District of Massachusetts. (June 30, 2016) *CVS to Pay $3.5 Million to Resolve Allegations that Pharmacists Filled Fake Prescriptions* [Press Release]. Available at https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filled-fake-prescriptions (last visited March 19, 2019).

pharmacy, which allegedly violated 21 U.S.C. 827(b)(2)(A) AND (b) AND 21 C.F.R. 1304.04(h)(3). CVS paid a $600,000 fine.[77]

35. December 22, 2016, Consent Order entered into between the United States and Kinray, LLC, a subsidiary of Cardinal Health.[78]

36. December 23, 2016, Cardinal Health agreed to pay a $34 million civil penalty to the DEA to resolve allegations that it failed to report suspicious orders and meet its obligation under the CSA in Florida, Maryland, New York, and Washington.[79]

37. January 5, 2017, McKesson Corporation entered into an Administrative MOA with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; LaCrosse, Wisconsin; Lakeland, Florida; Landover, Maryland; La Vista, Nebraska; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California.[80]

38. January 18, 2017, Walgreens agreed to pay $200,000 following an investigation by the Massachusetts Attorney General's Office found that Walgreens failed to track the opioid use of high-risk patients in the state's Medicaid program.[81]

39. March 9, 2017, Rite Aid paid $834,200 to the United States to settle claims that Rite Aid pharmacies in Los Angeles, California dispensed and/or recorded controlled substances using a medical practitioner's incorrect or invalid DEA registration number.[82]

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[77] CVS-MDLT1 000060830 – 000060838.

[78] *United States of America v. Kinray, LLC*, Case #16 Civ. 8767-RA. Available at https://www.justice.gov/usao-sdny/press-release/file/920806/download (last visited March 19, 2019).

[79] United States Attorney's Office, Middle District of Florida. (December 23, 2016) *United States Reaches $34 Million Settlement with Cardinal Health for Civil Penalties Under the Controlled Substances Act* [Press Release]. Available at https://www.justice.gov/usao-mdfl/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under (last visited March 19, 2019).

[80] United States Department of Justice. (January 17, 2017) *McKesson Agrees to Pay record $150 Million settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs* [Press Release]. Available at https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders (last visited March 19, 2019).

[81] Associated Press, "Walgreens to pay $200k, change opioid procedures," The Washington Times, January 19, 2017, available at https://www.washingtontimes.com/news/2017/jan/19/walgreens-to-pay-200k-change-opioid-procedures/) (last visited March 11, 2019).

[82] United States Attorney's Office, Central District of California. (March 9, 2017) *Rite Aid Corporation Pays $834,300 to Settle Allegations of Violating the Controlled Substances Act* [Press Release]. Available at https://www.justice.gov/usao-cdca/pr/rite-aid-corporation-pays-834200-settle-allegations-violating-controlled-substances-act (last visited March 19, 2019).

40. June 30, 2017, the United States Court of Appeals for the District of Columbia Circuit published an opinion denying the Masters' petition of review and upholding the Final Order.[83]

41. On July 5, 2017, a settlement was reached among the United States and the DEA and CVS Pharmacy, Inc. The settlement was the result of an investigation began by the DEA as a result of "an increase in the number of thefts and explained losses of Hydrocodone…" at numerous Eastern District of California CVS retail stores. The settlement resolved claims for the following misconduct: 1) failure to "provide effective controls and procedures to guard against theft and diversion of controlled substances (*see* 21 C.F.R. §1301.71(a)) and failure to notify DEA of certain thefts or significant losses of controlled substances within one business day of the discovery (*see* 21 C.F.R. §1301.74(c)); 2) failure to maintain schedule 3-5 invoices (21 CFR §1304.04(a)); 3) failure to maintain Schedule 3-5 records separate from non-controlled substance records (21 CFR §1304.04 (h)(3)); 4) failure to conduct a Biennial Inventory on one specific day (21 CFR §1304.11(c)); 5) failure to maintain complete and accurate records (21 CFR §1304.21(a)); 6) failure to record the date of acquisition of controlled substances (21 CFR §1304.22(c), 1304.22(a)(2)(iv); 7) failure to record the amount received on Schedule 3-5 invoices (21 CFR §1304.22(c)); 8) failure to record the amount received and the date received on DEA 222 forms (21 CFR §1305.13(e)); 9) failure to maintain DEA-222 forms (21 CFR §1305. 17(a)); and 10) failure to maintain DEA-222 forms separate from other records (21 CFR §1305. 17(c)). CVS admitted that between April 30, 2011 and April 30, 2013 the retail stores violated their recordkeeping obligations, but it denied that the recordkeeping obligations caused any diversion. CVS paid a fine of $5,000,000.00.[84]

42. July 7, 2017, Department of Justice/DEA and Mallinckrodt entered into a Memorandum of Agreement to resolve allegations that if failed to maintain effective controls to prevent diversion and to detect and report suspicious orders.[85]

43. January 24, 2018, the U.S. Attorney's Office entered into settlement with Rite Aid for improper sales of the meth precursor pseudoephedrine.[86]

44. On June 15, 2018, a settlement was reached among the United States and the DEA and CVS Health. The settlement resolved claims that between February, 2013 and January,

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[83] *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017).

[84] CVS-MDLT1 000060856-000060871.

[85] Administrative Memorandum of Agreement between DEA and Mallinckrodt, plc and its subsidiary Mallinckrodt, LLC, dated July 7, 2017. Available at https://www.justice.gov/usao-edmi/press-release/file/986026/download (March 19, 2019).

[86] United States Attorney's Office, Southern District of West Virginia. (January 24, 2018) *U.S. Attorney's Office enters settlement with Rite Aid based on improper sales of meth precursor pseudoephedrine* [Press Release]. Available at https://www.justice.gov/usao-sdwv/pr/us-attorneys-office-enters-settlement-rite-aid-based-improper-sales-meth-precursor (last visited March 11, 2019).

2015, CVS failed to report to the DEA in writing, within one business day of discovery, thefts or significant losses of controlled substances, including hydrocodone, from certain Long Island CVS Pharmacy retail stores, as required by 21 C.F.R. §1301.76(b). CVS agreed to pay a $1,500,000.00 fine. (CVS-MDLT1-000060839 – 000060846).

45. On July 29, 2018, a settlement was reached the among the United States and the DEA and CVS Pharmacy, Inc., to resolve claims related to a November 2013 inspection of a CVS Pharmacy in Calera, Alabama. The settlement resolved claims that CVS violated the CSA, as a result of violations of : (1) 21 C.F.R. 1305.13(c) (requirement to record the amount received and/or the date received on DEA 222 forms); (2) 21 C.F.R. 1304.21(a) (requirement to maintain complete and accurate records); and (3) 21 C.F.R. 1304.21(a) and/or (d) (requirement to document the number of packages received or the date package received on Schedule III through V purchase invoices). CVS agreed to pay a $1,000,000 fine.[87]

46. August 21, 2018, CVS agreed to pay $1 Million to settle allegations that CVS stores in Alabama failed to keep adequate records in violation of the Controlled Substances Act.[88]

47. December 31, 2018, the DEA and the Rhode Island Attorney General announced $300,000 settlement with Rite Aid for filling prescriptions of Schedule III controlled substances in excess of statutory maximums.[89]

11. INDUSTRY GUIDELINES - Healthcare Distribution Alliance

A large number of drug distributors and manufacturers are members of The Healthcare Distribution Alliance (HDA), a trade organization that provides industry information, providesguidance on best practices, industry standards, regulation/legal changes, and other related services.

A review of the website for The Healthcare Distribution Alliance (HDA) provided the following history of the organization.[90] The Western Wholesale Druggists' Association (WWDA) was formed on March 15, 1876 and consisted of 95 wholesale druggists. In 1882 the WWDA

[87] CVS-MDLT1-000060812 –000060821.

[88] United States Attorney's Office, Northern District of Alabama. (August 21, 2018) *CVS Pharmacy Pays $1 Million Penalty in Settlement with DOJ for Violations of the Controlled Substances* [Press Release]. Available at https://www.justice.gov/usao-ndal/pr/cvs-pharmacy-pays-1-million-penalty-settlement-doj-violations-controlled-substances-act (last visited March 19, 2019)

[89] United States Drug Enforcement Administration. (December 31, 2018) *DEA and Attorney General Kilmartin announces $300,000 settlement with Rite Aid for filling prescriptions of Schedule III controlled substances in excess of statutory maximums* [Press Release]. Available at https://www.dea.gov/press-releases/2018/12/31/dea-and-attorney-general-kilmartin-announces-300000-settlement-rite-aid (last visited March 11, 2019).

[90] *See* https://www.hda.org/ (last viewed on March 20, 2019).

became the National Wholesale Druggists Association (NWDA) that was representing distribution companies as an advocate in the distribution industry.

In 2000 the NWDA organization was renamed Healthcare Distribution Management Association (HDMA). The website stated the organization changed reflected the "Association's vision of a progressively more efficient and effective distribution system." In 2016 the HDMA changed names to the Healthcare Distribution Alliance (HDA). The website states the following, "Now headquartered in Arlington, Virginia, HDA represents 36 distribution companies — national, regional and specialty — as well as more than 130 manufacturer and more than 50 service provider/international members, respectively. These members serve more than 200,000 licensed healthcare providers, delivering over 15 million lifesaving products to these outlets every day. But just as in 1876, HDA's mission has remained the same, which is to protect patient safety and access to medicines through safe and efficient distribution; advocate for standards, public policies and business processes that enhance the safety, efficiency and value of the healthcare supply chain; and, create and exchange industry knowledge and best practices."

NWDA 1984 Suspicious Order Monitoring Policy

A review of Cardinal Health discovery material revealed a thirty-eight page document from 1984 by NWDA which was a draft outline of a suspicious order monitoring system. The documents can be found in the Cardinal Health discovery material in a group of documents that begin with a cover page containing, "NWDA Suspicious Order Monitoring System" with this stamped information, "Received Jun 21 1993 by Folsom." [91]

The first seven pages of the document describes some of the elements of a suspicious order system. These seven pages do not contain a date indicating when the system was designed. There are two DEA letters in the documents that do identify a date which are letters from the DEA. These DEA letters provide comment and guidance to NWDA in regards to the suspicious order system. The first DEA letter was addressed to Mr. Ronald J. Streck, Vice President of Government Affairs (NWDA) and signed by G. Thomas Gitchel, Acting Chief Diversion Operations Section (DEA). The letter contained a stamped date of April 27, 1984, which details a meeting between the two on April 13, 1984. This letter stated the DEA reviewed a draft form of the suspicious order monitoring system. This DEA letter contained the following comment:

> The NWDA's draft format for a suspicious order monitoring system provides as excellent framework for distributor registrants to "…design and operate a system to disclose to the registrant suspicious orders of controlled substances." (21 CFR 1301.74(b).) However, I am compelled to note, as I have in our previous discussions, that any automated data compliance processing system may provide the means and mechanism for compliance when the data is carefully reviewed and monitored by the wholesaler. As previously discussed, an after-the-fact computer printout of the sales data does not relieve a registrant of its responsibility to report

[91] The group of documents described in this section can be found in the Cardinal Health discovery material with a Bates stamp range of CAH_MCL2804_01465723 to CAH_MCL2804_01465761.

> excessive or suspicious orders when discovered. I am enclosing a copy of your draft with my pen-and-ink changes."[92]

The second DEA letter was addressed to Mr. Ronald J. Streck, Vice President of Government Affairs (NWDA), signed by G. Thomas Gitchel, Acting Chief Diversion Operations Section (DEA) that was stamped with a date of May 14, 1984, which appeared to be a follow-up communication from the April 27, 1984 letter. This letter details that there was a NWDA meeting that was attended by DEA employee David Walkup. This DEA letter contained the following comment:

> I want to assure you that DEA fully supports NWDA's effort to introduce a uniform reporting system among its members. This system, as proposed, will meet the reporting requirements of 21 CFR 1301.74(b). However, I want to make it clear that the submission of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of reporting excessive or suspicious orders. DEA has interpreted "orders" to mean prior to a shipment.[93]

The background section of the system details it was created in co-operation with the DEA. Further, the document states that the DEA may be providing some variances and limits that would be incorporated into the suspicious order system.

On page 7 of the suspicious order system document is "Section IX" that contains the following statement: "Single orders of unusual size or deviation must be reported immediately. The submission of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of report these excessive or suspicious orders. DEA has interpreted "orders" to mean prior to a shipment." This statement along with the letter from DEA is an important communication that identifies the DEA was requiring the suspicious order system to identify single orders of controlled substances that must report immediately prior to being shipped.

2008 Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Report Suspicious Orders and Preventing Diversion of Controlled Substances.

In 2008 the HDMA posted on their website industry compliance guidelines that were titled, "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances." In the introduction section of the document appeared this comment:

> At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support security of controlled substances they deliver to their customers. Due Diligence can provide a greater level of assurance that those who purchase CS from distributors intend to dispense them for legally acceptable purposes. Such due diligence can reduce the possibility that

[92] CAH_MDL2804_01465723, 01465732.

[93] CAH_MDL2804_01465723, 01465734.

controlled substances within the supply chain will reach locations they are not intended to reach.[94]

On October 17, 2008, DEA Chief Counsel Attorney Wendy H. Goggins sent a written statement to HDMA President and CEO John M. Gray commending the HDMA for their efforts to assist their members in fulfilling the obligations regarding the Controlled Substance Act and corresponding regulations.[95]

The HDMA compliance guidelines document contains a general framework for a basic suspicious order monitoring system.[96] The document contains the following elements with accompanying suggested guidelines:

1. Know Your Customer Due Diligence
2. Monitoring for Suspicious Orders
3. Suspend/Stop an Order of Interest Shipment
4. Investigation of Orders of Interest
5. File Suspicious Order of Interest
6. Employees, Training and Standard Operating Procedures (SOPs)
7. Additional Recommendations
8. Glossary of Abbreviations

Although there are several areas or concerns which might render a suspicious order monitoring system less effective, the guidance provided by HDMA does contain several key elements that are consistent with compliance with 21 C.F.R. Section 1301.71(a) and 1301.74(b). Some of the keys areas of the guidance are the following:

1. Recommending distributors conduct thorough due diligence investigations that are documented and retained is essential in establishing a customer and providing a history for any further compliance actions or investigations.[97]

2. Guidance for a distributor to develop an electronic suspicious order system as detailed in a standard operation procedure, although not required by regulation, demonstrates HDMA recognizes the manual review of orders for deviations in size, frequency, or pattern would render it ineffective.[98]

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[94] February 10, 2012 Declaration of Joseph Rannazzisi, CAH_MDL_PRIORPROD_DEA12_00014479, 00014512.

[95] CAH_MDL_PRIORPROD_DEA12_00000825.

[96] CAH_MDL_PRIORPROD_DEA12_00000826.

[97] CAH_MDL_PRIORPROD_DEA12_00000826, 00000829-00000832.

[98] CAH_MDL_PRIORPROD_DEA12_00000826, 00000832.

3. Separating customers by business activity or class of trade is an essential system element. Further enhancement for monitoring and setting averages would be to form subgroups by the size of the customer.[99]

4. Recommending of placing the controlled substances being monitored into groups or families provides a starting point for setting an average and monitoring. Only monitoring drug families and failing to evaluate the unusual order size, pattern, or frequency of any specific drug within a drug family has a much higher probability of failing to identify diversion of specific highly abused drugs.[100]

5. Thresholds are set as averages shipped to a customer's facility that are consistent with that class of customer. Threshold are recommended to calculated for single orders and average monthly orders per family, per customer, and class of trade. Thresholds should utilize the information obtained in the due diligence investigation. A sales history of a minimum of six months and maximum of 24 months is recommended. Thresholds for new customer accounts should be established at the lowest level indicated by the due diligence investigation. An important component is the periodic review of cumulative orders for the customer to evaluate purchasing trends. [101] Note: The use of a six-month average does not provide a sufficient purchase history for establishing accurate thresholds.

6. A distributor should consider allowing use of alternative criteria, outside of the suspicious order system, to be utilized to identify a suspicious order.[102]

7. On Page 9, Section III in the section titled, SUSPEND/STOP AN ORDER OF INTEREST SHIPMENT, there is clear guidance from HDMA of what action should be taken by a distributor when an order exceeds a threshold which is contained in the following statement, "If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest."[103]

8. Recommending if an order meets or exceeds a threshold the distributor examine the order further. The examination aids the distributor in deciding to either fill the order and ship or to continue to hold the order. This section also states, "Further examination will also aid in determining whether the and when to report the order to DEA under 21 C.F.R. Section 1301.74(b)."[104]

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[99] CAH_MDL_PRIORPROD_DEA12_00000826, 00000833.

[100] *Id.*

[101] *Id.*

[102] *Id.* at CAH_MDL_PRIORPROD_DEA12_00000826, 00000834.

[103] *Id.*

[104] *Id.*

9. The following statement is made in regard to an order of interest, "The drug or drugs that cause an order to become an order of interest should not be shipped to the customer placing the order while the order is an order of interest."[105]

12. A customer interview should be conducted in regards to order. Any information provided by the customer should be verified and documented.[106]

13. All investigations conducted by the distributor should be "fully documented," and all records retained in an appropriate section. A critical element of guidance states the following, "The documentation should include a clear statement of the final conclusion of the investigation, including why the order investigated was (or was not) determined to be "suspicious." The statement should be signed and dated by the reviewer."[107]

15. Order determined to be "suspicious" should be reported immediately upon being so determined.[108]

18. The following guidance was provided for the content of the standard operating policy:

a. Describe how an initial review and investigation will be conducted;

b. Reflect the distributor's and its customers' business conditions;

c. Are sufficiently flexible to adjust the review/investigation to address the individual product/order/customer circumstances that are likely to occur;

d. Include a process and/or guidance/criteria for making the final determination that an order is, or is not, "suspicious";

e. Define a process for reporting to DEA under 21 C.F.R. Section 1301.74(b); and

f. Define a process for allowing release of a shipment, or cancellation of an order, as appropriate.[109]

19. If a distributor concludes an order is suspicious after conducting an investigation it is recommended the distributor make a determination whether they will subject future orders from the same customer for the same drug product to more rigorous scrutiny and/or consider whether to cease filling all future orders of that drug product or all controlled substances.[110]

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[105] *Id.*

[106] *Id.* at CAH_MDL_PRIORPROD_DEA12_00000826, 00000835.

[107] *Id.* at CAH_MDL_PRIORPROD_DEA12_00000826, 00000836.

[108] *Id.*

[109] *Id.* at CAH_MDL_PRIORPROD_DEA12_00000826, 00000837.

[110] *Id.*

12. DEA CHEMICAL HANDLERS MANUAL

Cardinal Health (and others) have responded to discovery referencing the DEA's Chemical Handlers Manual and/or the 1998 Reno Report as "guidance" provided by the DEA regarding its suspicious order monitoring system for Schedule II and III controlled substances, including prescription opiates.[111] It is worth noting that these guidelines relate to "Listed Chemicals", rather than Schedule II and III controlled substances, primarily focused on the sale of chemicals used to make illicit methamphetamine. "Suspicious orders" of Listed Chemicals are defined by 21 USC § 830(b)(1)(A) as orders of "extraordinary" size [based on a formula which generally multiples a monthly base weight average per base code by a multiplier (3x)]. Notably, the Chemical Handlers Manual also mandates:

> **When a regulated person suspects that an order may be intended for illicit purposes, good practice requires that every reasonable effort be made to resolve those suspicions. In addition to making required reports, the transactions should not be completed until the customer is able to eliminate suspicions.**[112]

Relying upon a threshold of "extraordinary" size fails to detect orders of "unusual size" and is not compliant with 21 CFR 1301.74(b). Nor is shipping suspicious orders after reporting. Further, reliance on this threshold also does not detect orders of unusual pattern or frequency.

B. Key Structural Role and Critical Operational Importance of These DEA Registrants' Effective Controls for the Prevention of Diversion and Design and Operation of Suspicious Order Monitoring Programs

Registrants engaged in actively distributing or manufacturing controlled substances must design and implement measures that maintain effective controls to prevent diversion. These measures should be documented as a standard operating policy for the company and be distributed to all relevant employees. These standardized policies should be designed by distributors and manufacturers to take the utmost precautions to prevent diversion by maintaining the "closed system" of distribution. Included below are some key components that one would expect to see an operational system designed to maintain effective controls against diversion.

- Registrants must have a comprehensive system in place and conduct an investigation on a customer who will be purchasing controlled substances. The following are some of the activities utilized to establish a new customer:
    - The review to establish a new customer and begin distribution of controlled substances is a critical 1st step to ensures a potential customer has a business plan consistent with compliance to the Controlled Substances Act. The review should confirm the information provided by the potential customer is accurate. One commonly used procedure by distributors is to utilize a customer questionnaire which asks a series of questions similar to the following:

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[111] *See, e.g.*, CAH_MDL_PRIORPROD_HOUSE_0002207; CAH_MDL_PRIORPROD_DEA07_01198690.

[112] CAH_MDL_PRIORPROD_DEA07_01198690, 01198713.

VII. Conclusion

I reserve the right to amend or supplement my opinions in this matter considering any new or additional information.

James E. Rafalski

Date: 2/4, 2020

STATE OF MICHIGAN

COUNTY OF Wayne

JAMES E. RAFALSKI, being duly sworn, deposes and says: If called upon to testify in this matter, I would testify to the facts and opinions set forth in the foregoing report.

Sworn to before me this, the 4th day of February, 2020.

Notary Public

Shonta` Turman
Notary Public, State of Michigan
County of Wayne
My Commission Expires 12-21-2021
Acting in the county of Wayne